

Consumers for Dental Choice

1616 H St., N.W., 8th floor
Washington, DC 20006
Ph. 202.347-9112; fax 347-9114 1 8 7 7 T E X T 1 5 5 7 2 2
www.toxicteeth.org

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David Feigal, M.D.-M.P.H., Director
Center for Devices & Radiological Health
FDA
Rockville

(Sent to AXB@cdrh.fda.gov: Adrian Burns)

Dear Dr. Feigal:

Dental Devices' proposed rule is probably the most anti-scientific document ever produced under the FDA's name. It chooses to present the dogma of the American Dental Association -- who has never, repeat never, done one peer-reviewed study proving the safety of mercury fillings and does not even have a peer-reviewed journal -- as "science." In its zeal to protect dental economics over consumer protection, Dental Devices goes in the opposite direction of FDA policies, which is AGAINST mercury in food, drugs, and devices. The February 2002 Consumer Update -- a pro-mercury puff piece ratifying the ADA / manufacturer position (the manufacturers pay the ADA for promoting the product, a totally unethical position) -- contains plenary deceptive statements and outright falsehood about the WHO, Health Canada, and the state of the controversy of mercury; it also suggests the agency has made up its mind about the controversy before public comment even began.

The proposed rule, commentary, and Consumer Update are antithetical to established scientific procedures and to FDA policies:

- Unlike the FDA's normal practices, it prefers relying on non-peer reviewed articles -- almost entirely from the non-peer-reviewed "Journal of the American Dental Association" -- instead of the peer-reviewed articles that point to the health risks of mercury fillings. For an issue as important as whether a toxic material may safely be implanted into children and pregnant women, both the quantity and the quality of the cited sources is pathetic from a scientific viewpoint.
- Unlike the FDA's policies on mercury, it trivializes the dangers it poses, several times dismissing mercury toxicity from mercury fillings because mercury toxicity also can be obtained from "water and food."
 - In fact, the FDA is quite concerned about mercury from food, as evidenced from its recent hearings about fish warnings.
 - It mischaracterizes mercury toxicity as an "allergic reaction," part of the ADA's promotional scheme for mercury fillings.
- Unlike FDA policies of relying on recent science, the scientific advisory panel last held hearings eight years ago. By refusing to hold hearings since, Dental Devices has missed the following developments, all against mercury fillings:

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- The many peer-reviewed studies condemning mercury dental fillings, by Professors Haley, Lorscheider, Vimy, Summers, Aposhian, Chang, etc.;
 - The Health Canada report, recommending no mercury fillings for children, pregnant women, and those with kidney problems or braces;
 - The contraindication warnings by the manufacturer Dentsply, advising dentists to stop giving mercury fillings to children, pregnant women, and those with kidney problems, braces, or mercury allergies;
 - The federal court decision holding that Proposition 65 warnings (California) issue for mercury dental fillings (which Dental Devices apparently wants to overturn);
 - The ending of mercury in other health care uses, such as in vaccines, thermometers and contact lenses.
 - The Watson-Burton bill, H.R. 4163, with five more co-sponsors to date, which would abolish mercury dental fillings;
 - State bills, similar to Watson-Burton, introduced in, to date, Alabama, Arizona, California, Georgia, and Illinois.
 - The 1999 PHS report discussed in footnote 1.
 - The resolution of the California Medical Association (2000) favoring phasing out of all health care products that contain mercury;
 - The resolution of the American Public Health Association (1999) favoring phasing out of all health care products that contain mercury;
 - The official paper of the American Pediatric Medical Association advising physicians to recommend mercury-free dentists to patients concerned about exposure to mercury;
 - The emergence of Health Care Without Harm as an organization opposed to mercury in health care products;
 - The creation of Consumers for Dental Choice (1996), a consumer group favoring, first, informed consent, and second, an end to mercury dental fillings;
 - The creation of the Coalition to Abolish Mercury Dental Fillings (2001), an umbrella group supporting policies ending mercury in dentistry;
 - State laws directing specific warnings issue: Arizona (2000), Maine (2001), and New Hampshire (2002);
 - The implementation of a 1992 California statute requiring a “fact sheet” on the risks of mercury fillings, so blithely ignored by the Dental Board that the Legislature shut down the Board in 2001;
- Unlike FDA policy that seeks a “diversity of scientific views,” as promised by Dr. McClellan at his confirmation hearings on Monday (October 7), Dental Devices, in its listing of testimony from those 1994 hearings, heard one viewpoint: the ADA pro-mercury fillings position. Dental Devices has to date refused to create a new panel, refusing to say why. The make-up of a new panel would no doubt be an event feared by the ADA. The constituency make-up of such a panel needs to reflect current realities, not those of a decade ago: professional societies and consumer groups opposed to allowing toxic mercury to be implanted in our children’s mouths.

- Unlike FDA policies putting consumers first, it takes the side of dental economics over the children and pregnant women of America. *That Dental Devices would state as its goal (in the Consumer Update) to stop warnings for children and pregnant women pits the enormous powers of your agency against the most defenseless members of this society.*
- Unlike the FDA tradition of being first in safety, it tries to relegate the FDA in last place in protecting consumers against mercury toxicity.
 - Canada opposes mercury fillings for children, pregnant women and those with renal disease or braces.
 - The U.K. says pregnant women should not get mercury fillings.
 - Norway is going mercury free in 2003.
 - Sweden went mercury-free for health as well as environmental reasons, as stated in the public comment to the proposed rule.
 - The UN, meeting in Geneva last month, listed mercury from dental fillings as one of the potential sources of environmental and public health harm.

Worst of all, the rule contains a massive infusion of downright intellectual dishonesty:

- (1) It pretends the last word from the Public Health Service was its 1993 report. In fact, the 1999 report, U.S. Public Health Service: Agency for Toxic Substances and Disease Registry, Toxicological Profile in Mercury, (Update) (1999) contains startlingly different conclusions.¹ (The ADA likewise pretends there is no 1999

¹ I. MERCURY EXPOSURE

Page 7: "The mercury from dental amalgam may contribute 0 to more than 75% of your total daily mercury exposure, depending on the number of amalgam fillings you have, the amount of [and levels of mercury in the] fish you consume, ... and exposure from less common sources of mercury."

II. AMALGAM AND MERCURY EXPOSURE

Page 29: "The general population is commonly exposed to mercury primarily from two sources: (1) eating fish ... or (2) from the release of elemental mercury from the dental amalgam used in fillings."

III. AMALGAM AS LARGEST POTENTIAL SOURCE OF MERCURY

Page 439: "Dental amalgams potentially represent the largest single contributing factor of mercury exposure in some individuals with large numbers (>8) of amalgam fillings." The study then spends several pages going through research indicating large exposure from amalgam fillings, several such studies showing a larger exposure than fish.

IV. MOTHER TO BRAIN OF FETUS

Page 12: "Methylmercury that is in the blood of a pregnant woman will easily move into the blood of the developing child and then into the child's brain and other tissues." Methylmercury will change into organic mercury, and "remain [in the brain] for a long time."

Page 455: "Significant health risks, including numerous neuropathological and neurobehavioral effects, are associated with prenatal exposure to methylmercury."

V. MOTHER TO NURSING INFANT

Page 12: "As with inorganic mercury, some of the methylmercury in a nursing woman's body will pass into breast milk."

VI. CHILDREN

update; it is hard to conceive that the convergence of the ADA and Dental Devices on this matter is coincidental.)

- (2) It dishonestly equates mercury toxicity with “an allergic reaction.” Every scientist knows there is a huge difference. Where would such a preposterous idea originate? From the ADA’s economic protectionist position.²
- (3) It cites a W.H.O. committee of dentists and represents it as “the W.H.O.” Everyone else at the FDA knows the difference. In fact, the W.H.O. has said, “There is no safe level of mercury”!
- (4) It absolutely miscites Health Canada as having no problems with mercury fillings. In fact, back in 1996 Health Canada wrote a letter to every dentist in the country (in French and in English) asking them to pay heed to its recommendations. And what are the recommendations of Health Canada?
 - No mercury fillings for children.
 - No mercury fillings for pregnant women
 - No mercury fillings for persons with kidney problems
 - No mercury fillings for persons with braces

Page 455: “Children are not small adults.” The report shows how children may have greater exposure and have greater risks from mercury.

VII. BRAIN DAMAGE

Page 13: “Permanent damage to the brain has also been shown to occur through exposure to sufficiently high levels of metallic mercury.”

VIII. NEUROLOGICAL EFFECTS

Page 276: “The nervous system is the primary target organ for elemental and methylmercury-induced toxicity.”

IX. DEVELOPMENTAL EFFECTS

Page 280: “Mercury is considered a developmental toxicant.”

X. CORRELATION OF AMALGAM AND REDUCED IMMUNITY

Page 300-01: “Accumulation of heavy metals from dental amalgam, as well as from other sources, may lower the threshold of an individual metal to elicit immune aberrations, which could lead to overt autoimmunity

XI. EFFECT ON DENTISTS

Page 63: “Dentists with an average of 5.5 years of exposure to low levels of mercury showed impaired performance on several neurobehavioral tests.”

XII. EFFECT ON WOMEN DENTAL PERSONNEL

Page 278: “Reproductive effects. ... Female dentists and dental assistants exposed to metallic mercury vapors had increased reproductive failures (spontaneous abortions, stillbirths, and congenital malformations) and irregular, painful, or hemorrhagic menstrual disorders. Correlations were observed between the incidence of these effects and hair mercury levels.”

² The ADA is massively invested in the economic success of amalgam, so much so that it sued a lawyer for calling mercury fillings unsafe. (The lawsuit, inherently, presupposes an economic interest in order to have party status.) The ADA held patents on amalgam, so adopted a gag rule to stop dentists criticizing the product. The patents have expired, but not the gag rule. Instead, the ADA charges economic royalties to manufacturers whose products it endorses and promotes. The AMA considers such economic hucksterism to be unethical.

- o A limit of one mercury filling for teenagers.
- (5) It allows that mercury fillings is the largest source of mercury toxicity (citing Health Canada), then proceeds to ignore that incredibly salient point because the *ADA Journal* says it doesn't matter.
- (6) It pretends that dental fillings are not an implant, in order to skirt legal requirements.
- (7) It pretends there is no environmental effect to dumping mercury into our nation's water, when in fact dental offices are the leading source of mercury in the nation's wastewater. See Dentist the Menace: The Uncontrolled Release Of Mercury, by the Mercury Policy Project, Health Care Without Harm, The Sierra Club, and Toxics Action Center.³
- If the FDA would make mercury fillings a Class III, then the mercury pollution problem would be reduced significantly.
- (8) Even though every scientist knows that mercury toxification depends in part on quantity, the report flippantly equates the (literally) GRAMS of mercury in the fillings with the billionths of a gram that might be present in the outside air. Again, only the ADA agrees with Dental Devices in equating mercury from fillings with mercury from the air. The ADA's excuse is that it has an economic stake to protect. Dental Devices has no excuse for such intellectual chicanery.
- (9) It pretends that dentistry is not divided, even suggesting that the decline of amalgam fillings has no connection to the expanding number of dentists who oppose mercury fillings and consumers who feel likewise. In fact, three national dental societies categorically oppose mercury dental fillings because of their adverse health and environmental effects.
- (10) Although Dental Devices knows or should have known about existing state laws requiring disclosure of risks – a highly salient point that any impartial regulator would have included in the discussion -- it makes no listing of them.
- (11) It seeks no inquiry as why manufacturers have issued contraindication warnings against pregnant women and children. One would think

The timing of the regulation clearly shows a political power play aimed directly at opponents of mercury fillings. After sitting for eight years, Dental Devices acted in the face of Congresswoman Watson's announcement that she would ban such fillings for children and pregnant women, and the introduction or announcement of such bills regulating dentists who administer such poisons to children in about ten states. Congress is considering going one way – a phaseout -- while the FDA is pulling hard in the other direction. The FDA took no such step when the Senate acted to ban thermometers.

³ Released June 5, 2002. Available at <http://www.mercurypolicy.org/new/documents/DentistTheMenace.pdf>; also available at http://www.noharm.org/library/docs/Dentist_the_Menace.pdf.

The position is especially harmful to poor people, as it will institutionalize mercury filling for the poor. Small wonder that the NAACP supports the Watson-Burton bill, as does the National Black Caucus of State Legislators -- two organizations which put people above economics.

That a great federal agency would bail out a powerful trade association by actually trying to stop prevent states and manufacturers from protecting children and pregnant women -- instead of requiring protection for children -- is intolerable. We urge you to recognize you have been disserved by the Dental Devices section on this issue. Please withdraw the rule, form a new Advisory Panel with diverse viewpoints, and welcome rather than fight the emerging science. The science, objectively analyzed, will plainly demonstrate that mercury fillings are a Class III device.

Sincerely


Charles G. Brown
Counsel